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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,196	01/17/2002	R. Eric Montgomery	04163-00138	6812
26565	7590	07/28/2004	EXAMINER	
MAYER, BROWN, ROWE & MAW LLP 190 SOUTH LASALLE ST CHICAGO, IL 60603-3441			KRASS, FREDERICK F	
		ART UNIT		PAPER NUMBER
		1614		
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/050,196	MONTGOMERY, R. ERIC	
	<b>Examiner</b>	<b>Art Unit</b>	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 April 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-42 and 49-63 is/are pending in the application.
- 4a) Of the above claim(s) 13-17,38-42 and 49-53 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-37 and 54-63 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9-17-03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

### **Abstract**

The abstract of the disclosure is objected to because it is not one paragraph in length. See the amendment dated 2/10/03, which added a second paragraph. Correction is required. See MPEP § 608.01(b).

### **Election of Species Requirement**

Applicant's election of 1) sodium hydroxide as the species of alkalizing agent and 2) hydrogen peroxide as the species of whitener, without traverse, is acknowledged.

Claims 13-17, 38-42 and 49-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

### **Claim Informalities**

Claim 33, first line, "include" should be pluralized.

### **Duplicate Claim Warning**

Applicant is advised that should claims 18-22 be found allowable, claims 54-58 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following claims also appear to be substantial duplicates:

- 1) Claims 34 and 62; and
- 2) Claims 37 and 63.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25, first line, there is no antecedent basis for "the alkalizing agent" in claim 23.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 18-37 and 54-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USP 5,098,303) in view of Coulson (USP 5,089,354).

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The primary reference discloses tooth bleaching gels containing peroxide bleaching agents such as carbamide peroxide and hydrogen peroxide (col. 5, lines 12-22). The prior art differs from the instant claims in that it is silent regarding an alkaline pre-treatment step, although it does clearly teach that before bleaching "it is recommended that the patient's teeth be clean of calculus and external stains". (See the passage spanning the bottom of col. 8 and the top of col. 9). In other words, the teeth should be cleaned before bleaching – an eminently common sense notion.

The secondary reference discloses an oral hygiene procedure in which cleaning efficacy is improved by pre-treating the teeth with an agent which blocks hydroxy groups on the tooth surface, such as sodium hydroxide, sodium carbonate or sodium bicarbonate, followed by brushing with a toothpaste. See col. 1, lines 56-64. An aqueous solution having a pH of 8 and comprising sodium carbonate (an alkaline compound which is also a buffering agent) is used in working example 2 (see col. 4, lines 20 and 21), and a composition comprising 0.50 percent trisodium orthophosphate and 0.15 percent NaOH (which would inherently form a buffered system), is used in working example 3. The secondary reference thus differs from the instant claims in that it does not disclose a subsequent whitening step.

It would have been obvious to have cleaned a patient's teeth in advance of using a peroxide bleaching process as disclosed by the primary reference by pre-treating with an alkaline agent, then brushed, motivated by the desire to provide the improved efficacy taught by the secondary reference for such treatments. Since teeth are naturally acidic, this would raise the pH on their surface. At the outermost surface layer, at least, the pH would be the same as that of the alkaline composition being applied thereto. Moreover, that pH would be "maintained" for the duration of contact, and for a short time thereafter.

2) Claims 18-37 and 54-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USP 5,098,303) in view of Goldemberg et al (USP 4,666,708).

The primary reference discloses tooth bleaching gels containing peroxide bleaching agents such as carbamide peroxide and hydrogen peroxide (col. 5, lines 12-22). The prior art

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differs from the instant claims in that it is silent regarding an alkaline pre-treatment step, although it does clearly teach that before bleaching "it is recommended that the patient's teeth be clean of calculus and external stains". (See the passage spanning the bottom of col. 8 and the top of col. 9). In other words, the teeth should be cleaned before bleaching – an eminently common sense notion.

The secondary reference discloses alkaline oral rinses having increased plaque (calculus) removing efficacy (col. 3, first four lines). The rinse is rendered basic through the incorporation of an alkaline agent, e.g. sodium carbonate (col. 4, line 58), which is also a buffer. Additional buffering agents such as sodium bicarbonate may be included as well; the final pH in all cases will be about 7.5 to 10.0. (Col. 5, lines 24-31).

It would have been obvious to have cleaned a patient's teeth in advance of using a peroxide bleaching process as disclosed by the primary reference with an alkaline rinsing solution, motivated by the desire to provide the improved efficacy taught by the secondary reference for such rinses. Since teeth are naturally acidic, this would raise the pH on their surface. At the outermost surface layer, at least, the pH would be the same as that of the alkaline composition being applied thereto. Moreover, that pH would be "maintained" for the duration of contact, and for a short time thereafter.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

